

## United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,797	06/24/2003	Thomas May	022956-0217	1008
21125 7	590 02/07/2006		EXAM	INER
	CCLENNEN & FISH DE CENTER WEST	BROWN, M	ICHAEL A	
155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			ART UNIT	PAPER NUMBER
			3764	
			DATE MAILED: 02/07/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)			
	10/602,797	MAY, THOMAS			
Office Action Summary	Examiner	Art Unit			
	Michael Brown	3764			
The MAILING DATE of this communication apperiod for Reply	pears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING D.  - Extensions of time may be available under the provisions of 37 CFR 1. after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period.  - Failure to reply within the set or extended period for reply will, by statut Any reply received by the Office later than three months after the mailine earned patent term adjustment. See 37 CFR 1.704(b).	OATE OF THIS COMMUNICATION 136(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from e, cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status					
3) Since this application is in condition for allowa					
Disposition of Claims					
<ul> <li>4)  Claim(s) 1-30 is/are pending in the application.</li> <li>4a) Of the above claim(s) is/are withdrawn from consideration.</li> <li>5)  Claim(s) is/are allowed.</li> <li>6)  Claim(s) 1-30 is/are rejected.</li> <li>7)  Claim(s) is/are objected to.</li> <li>8)  Claim(s) are subject to restriction and/or election requirement.</li> </ul>					
Application Papers					
<ul> <li>9) The specification is objected to by the Examiner.</li> <li>10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).</li> <li>11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.</li> </ul>					
Priority under 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of: <ol> <li>Certified copies of the priority documents have been received.</li> <li>Certified copies of the priority documents have been received in Application No</li> <li>Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> </ol> </li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>					
Attachment(s)					
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08 Paper No(s)/Mail Date 19-09-03.  S. Patent and Trademark Office	4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal F 6) Other:				

## **DETAILED ACTION**

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dreyfuss in view of with Gogolewski, along with Sasso.

Dreyfuss discloses in figures 1-7 a tissue fixation device, comprising an elongated body 108 formed of a biocompatible material (page 3, section 0038, lines1-2), having an outer surface (fig. 5), a proximal end (fig. 5), a distal end (fig. 5), a longitudinal axis (fig. 5), an internal cavity 136, extending into the body forming an opening in the proximal end (fig. 5) of the body, the cavity terminating proximal to the distal end (fig. 5), at least one opening (117, 118) formed in the outer surface of the body, the opening is in fluid communication with the internal cavity (fig. 5), the body is s pin, a portion of the outer surface of the body includes surface features (threads 116), the outer surface is smooth (at the lower end), the outer surface of the elongated body is porous (at 117, 118) the opening (117, 118) communicates with the cavity through a passage 126, the outer surface is non-porous (the upper end away from 117, 118), the elongated body has a substantially cylindrical shape (fig. 1) and the distal end is tapered at 114. However, Dreyfuss doesn't disclose the elongated body being formed of a bioresorbable material. Gogolewski teaches in figures 1-5 tissue fixation device

Application/Control Number: 10/602,797

Art Unit: 3764

that is formed of a bioresorbable material that is a polymer that includes carprolactone and poly (amino acids) (col. 5, lines 5-22). It would have been obvious to one having ordinary skill in the art at the time that the invention was made that the biocompatible fixation device disclosed by Dreyfuss could be fabricated out of the type of polymers as taught by Gogolewski in order to allow the fixation device to degrade in the body over a period of time. The length of the body, the diameter of the pin, the resorption profile of the pin being in the range of about 0.5mm to 5mm, the range of the diameter of the pore, the range of the number of openings and the range of the diameter of the at least one opening are design choices that aren't critical. Thus, these dimension provided no novelty over the prior art. The treatment material and the biologically material are intended use that weren't positively claimed (in claims 1-24). As for claims 25-30, Drevfuss discloses placing an adhesive on the ends of the graft 138. This adhesive could be injected into the channel or placed on the ends of the graft and inserted into the opening. However, Sasso provides a teaching for injecting an active material 88 into a fixation device 20 so the material flows through openings 32 in the fixation device. It would have been obvious to one having ordinary skill in the art at the time that the invention was made that the adhesive disclosed by Dreyfuss could be injected into the opening in order to used the adhesive to hold the graft in place. The different types of treatment material, the active material, the adhesive agent and the anchoring agent are old and well known in the surgical art. In order words, using either of these elements wouldn't involve and inventive step.

Page 3

## Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sapian, Vives and Ross each disclose a fixation device.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brown whose telephone number is 571-272-4972. The examiner can normally be reached on 5:30 am-4:00 pm Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gergory Huson can be reached on 571-272-4887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. Brown January 24, 2006

> MICHAEL A. BROWN PRIMARY EXAMINER

Midal G. Br